Nihon Kohden America, INC.
11/15/2011

Special 510(k) Notification
NetKonnect Remote Network Extension

DEC - 9 2011

510(k) Summary

1.1. Intended Use

The NetKonnect Remote Network Extension is intended to interface the Nihon Kohden monitoring network with networked client PCs to annunciate and display patient monitoring information to healthcare providers. The device is intended for use in real-time monitoring of routine patient status and alarm events. NetKonnect Remote Network Extension supplements the primary patient monitoring system by providing a forwarding mechanism for annunciating and displaying patient alarm events and event related information including vital signs values and waveforms.

1.2. Device/Package Labels

The proposed product labels for the device are located in Attachment 13 .

1.3. Proposed Packaging

Packaging is depicted in Attachment 13.

1.4. Instructions for Use

The proposed instructions for use (user manuals) are provided with each packaged device and are presented in Attachment 13.

1.5. Advertisement/Promotional Literature

To date no advertisement or promotional literature for the new has been created for distribution in the United States.

1.6. Contraindications, Precautions & Warnings

Warnings and cautions are listed in the Operator's Manual as shown in Attachment 13.

1.7. Indications for Use Statement

Indication for use statement is presented in Attachment 4.

DEVICE DESCRIPTION

2.1. Photographs/Engineering Drawings

The proposed drawings are provided in Attachment 13.

2.2. Physical Description

NetKonnect is a software product that runs on Microsoft .Net Framework. NetKonnect will communicate with Nihon Kohden patient monitoring devices by the direct network connection (NetKonnect-LT) or through the gateway (NetKonnect). NetKonnect will allow hospitals to provide full featured remote overview access capability to its clinicians inside the hospital and outside of hospital by using the dial-up connection or Internet connection at minimal cost.

2.3. Principles of Operation

Netkonnect has no user interface (except administrator functions) and performs all functions automatically without user intervention. When the network hosting NetKonnect is started, NetKonnect runs automatically and detects each of the Nihon Kohden devices on the patient monitoring network and establishes a vital signs and patient status communication connection with each one. Client PCs can communicate with NetKonnect to provide for remote monitoring of single or multiple patients. Remote monitoring function includes waveform and vital signs viewing, alarm notification and review of stored patient information.

2.4. Design Features

2.5. Device Specifications
The device specifications are provided in Attachment 16.

2.6. Accessories
NetKonnect is a software only product, there are no accessories.

2.7. Significant Changes that could affect Safety or Effectiveness or Intend Use.
There are no significant changes as compared to the predicate devices that would affect the safety or effectiveness of the device as intended for use.

COMPARATIVE INFORMATION

SPECIFICATION	Nihon Kohden NetKonnect Extension CGS-9003	Nihon Kohden CGS-9001 GWY 510k # K083271		Comments
Description of communication requirements	Receives and forwards waveform data using Nihon Kohden's proprietary "NET9" protocol language.	Same, but data must be converted		Predicate device also converts (translates) the data into a language that is supported by the 3rd party application. We have determined that this difference does not increase the risk of patient safety or affect the device from performing in the manner in which it is intended to operate from the predicate device CGS-9001
	Receives and forwards Numerical data using Nihon Kohden's proprietary "NET9" protocol language.	Same, but data must be converted		Predicate device also converts (translates) the data into a language that is supported by the 3rd party application. We have determined that this difference does not increase the risk of patient safety or affect the device from performing in the manner in which it is intended to operate from the predicate device CGS-9001
	Receives and forwards Alarm notification to other Nihon Kohden approved devices such as Central Nurse station using Nihon Kohden's proprietary "NET9" protocol language. When used with PC or portable device, no alarm notification is available	Same, but data must be converted		Predicate device also converts (translates) the data into a language that is supported by the 3rd party application. We have determined that this difference does not increase the risk of patient safety or affect the device from performing in the manner in which it is intended to operate from the predicate device CGS-9001
	Alarm notification is a	Same		

	secondary notification system and does not replace the primary alarm notification of the beside monitor			
	Communicates with bedside monitors and telemetry receivers via Ethernet	Same		
Communication design	Real time monitoring	Same		
OS requirements	Microsoft windows that support Win32 service processes	Same		

3.1. Intended Use

The NetKonnect Remote Network Extension is intended to interface the Nihon Kohden monitoring network with networked client PCs to annunciate and display patient monitoring information to healthcare providers. The device is intended for use in real-time monitoring of routine patient status and alarm events. NetKonnect Remote Network Extension supplements the primary patient monitoring system by providing a forwarding mechanism for annunciating and displaying patient alarm events and event related information including vital signs values and waveforms.

3.2 Physical Characteristics

The NetKonnect Remote Network Extension is a software only product available on CD Rom.

3.3 Target Population

The NetKonnect Remote Network Extension will not change the target population of the cleared monitoring devices that the patients are connected to. The device is available for use by medical personnel on all patient populations.

3.4. Product Labeling

I. Labeling

To date no advertisement or promotional literature has been created for distribution in the United States. Labeling for the currently marketed is located in Attachment 13.

II. Instructions for Use

Instructions for use are provided with each packaged device and are presented in Attachment 13.

III. Proposed Packaging

Packaging is presented in Attachment 13.

IV. Engineering Drawings/Photographs

Drawings of the device are provided in Attachment 13.

3.5. Substantial Equivalence

Substantial equivalence discussion can be found in attachment # 12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 9 2011

Nihon Kohden America, Inc.
c/o Mr. Steve Geerdes
Director or Quality Assurance and Regulatory Affairs
90 Icon
Foothill Ranch, CA 92610

Re: K112637
Trade/Device Name: NetKonnect Remote Network Extension
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: November 22, 2011
Received: November 30, 2011

Dear Mr. Geerdes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112637

Indications for Use Form

510(k) Number (if known): _____

Device Name: ___ **NetKonnect Remote Network Extension**

Indications for Use:

The NetKonnect Remote Network Extension is intended to interface the Nihon Kohden monitoring network with networked client PCs to annunciate and display patient monitoring information to healthcare providers. The device is intended for use in real-time monitoring of routine patient status and alarm events. NetKonnect Remote Network Extension supplements the primary patient monitoring system by providing a forwarding mechanism for annunciating and displaying patient alarm events and event related information including vital signs values and waveforms

The system is intended for use by qualified medical personnel within a hospital or clinical environment. The stimulator is available for use on any patients as determined by the qualified medical personnel.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K112637